REMARKS

The Official Action dated February 12, 2004 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, the specification is amended to omit hyperlinks. Claims 1-9 are cancelled and claims 10-20 directed to the elected subject matter and process claim 21 dependent thereon are presented. Support for these claims may be found in original claims 1-8 and in the specification, for example at pages 4 and 6. Claim 10 also recites a nucleotide sequence capable of hybridizing, along its full length, under stringent hybridization conditions, to a nucleotide sequence complimentary to the polypeptide coding region of a nucleic acid molecule as defined in (a). Although the phrase "along its full length" is not literally set forth in the present specification, Applicant submits that the teachings set forth in the present specification with respect to the nucleotide sequences identified by SEQ ID NO and nucleotide sequences homologous thereto indicate that hybridization along the full length of the nucleotide sequence is contemplated. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, the Examiner indicated that claims 1-7 and 9, and SEQ ID NOs: 1 and 2 are examined, and that withdrawn process claims that depend from or otherwise include all the limitations of a patentable product will be rejoined in accord with MPEP 821.04. Accordingly, rejoinder of process claim 21 is requested upon allowance of claim 10 from which it depends.

The disclosure was objected to because it contained embedded hyperlinks and/or other forms of browser executable code. In response to this objection, Applicant notes that it is not intended to have the hyperlinks recited in the specification as active links and therefore, the specification has been amended to omit the "http:www" and similar portions of the internet addresses. It is therefore believed that the objection to the specification has been overcome. Reconsideration is respectfully requested.

Claims 1 and 3 were objected to as reciting non-elected sequences. Claims 10-21 are directed to the elected sequences. It is therefore believed that the objection to the claims has been overcome. Reconsideration is respectfully requested.

In the Official Action, claims 1-7 and 9 were rejected under 35 U.S.C. §101 and under 35 U.S.C. §112, first paragraph, on the basis that the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The Examiner asserted that the specification does not identify the protein of SEQ ID NO: 2 as a tricarboxylate carrier or as a member of any known protein family and does not demonstrate activity or function of the protein or the nucleotide encoding the protein. The Examiner further asserted that although the specification identifies the tissues having the expression of SEQ ID NO: 1 and indicates the invention is to identify genes involved in metabolic disorders, the specification does not provide a direct correlation between the metabolic disorder and the protein.

These rejections are traversed and reconsideration is respectfully requested. More particularly, the present specification discloses at page 1, that the genes encode a group of polypeptides which are to be used for the diagnosis of metabolic diseases such as obesity and diabetes, and treatment of such diseases. As described in the specification, and as known in

the art, identification of genes involved in metabolic disorders and diabetes contributes to the development of predictive and therapeutic approaches (page 3, lines 10-12). Specifically, the specification discloses that the nucleic acid molecules according to the invention have numerous applications in techniques known to those skilled in the art of molecular biology in diagnosis of obesity and diabetes, as well as in identification of therapeutic agents, including hybridization probes, chromosome and gene mapping, production of sense or anti-sense nucleic acids, screening for new therapeutic molecules, and the like (page 5, lines 4-8). These techniques are discussed in further detail in the second full paragraph on page 5.

The present specification thus discloses a specific substantial asserted utility. According to the utility guidelines of the U.S. Patent and Trademark Office, a specific utility is a utility that is specific to the subject matter claimed. While a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed, the present specification is specific to the diagnosis and to the identification of agents useful in the treatment of specific metabolic diseases, particularly obesity and diabetes. Thus, a specific utility is disclosed. Further, according to the utility guidelines, a substantial utility is a utility that defines a "real world" use. The utility guidelines indicate, for example, an assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition defines a "real world" context of use in identifying potential candidates for preventive measures or further monitoring, and therefore has a substantial utility. Similarly, the presently claimed isolated nucleic acid molecule is disclosed as having a correlation to metabolic diseases, particularly obesity and diabetes, and therefore the present specification defines a "real world" context of use in diagnosing these specific diseases and identifying

potential candidates for treatment of the diseases. Thus, the present specification satisfies the utility guidelines for specific and substantial utility.

There is no requirement in 35 U.S.C. §101 or 35 U.S.C. §112, first paragraph, which requires Applicants to set forth data or results, particularly since the Examiner has not asserted, or provided any basis for asserting, that the disclosed utilities are not credible. It is therefore submitted that the disclosed utilities of the presently claimed isolated nucleic acid molecule in the diagnosis of metabolic diseases, specifically obesity and diabetes, as well as in the identification of agents useful in the treatment of such diseases, satisfies the utility requirements of 35 U.S.C. §101 and therefore teaches one skilled in the art how to use the claimed invention in accordance with the requirements of 35 U.S.C. §112, first paragraph, whereby these rejections have been overcome. Reconsideration is respectfully requested.

Claims 1, 2, 4-7 and 9 were rejected under 35 U.S.C. §102(b) as being anticipated by the Tang et al U.S. Patent No. 6,569,662. The Examiner referred to SEQ ID NO: 1016 referenced at columns 175-176.

This rejection is traversed and reconsideration is respectfully requested. More particularly, claim 10 is directed to an isolated nucleic acid molecule selected from the group consisting of: (a) a nucleic acid molecule consisting of a nucleotide sequence as shown in SEQ ID NO: 1, or a nucleotide sequence which is at least 90% homologous with a nucleotide sequence as shown in SEQ ID NO: 1; (b) nucleic acid molecules consisting essentially of a nucleotide sequence capable of hybridizing, along its full length, under stringent hybridization conditions, to a nucleotide sequence complementary to the polypeptide coding region of a nucleic acid molecule as defined in (a); and (c) nucleic acid molecules consisting

of a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence as defined in (a) or (b).

From the sequence matches relating to SEQ ID NO: 1 provided by the Examiner, it appears that SEQ ID NO: 1016 of Tang et al contains 1729 nucleotides. Accordingly, the isolated nucleic acid molecule selected from the group consisting of (a), (b) and (c) as set forth in claim 10 is clearly distinguishable from Tang et al. Anticipation under 35 U.S.C. §102 requires the disclosure in a single prior art reference of each element of the claims under consideration, *Alco Standard Corp. v. TVA*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). Applicant finds no teaching or reference by Tang et al of a nucleic acid molecule consisting of a nucleotide sequence as claimed. Rather, Tang et al provide a significantly larger, different nucleotide sequence. Thus, Tang et al do not disclose each element of claim 10 and therefore do not support a rejection of this claim, or the claims dependent thereon.

It is therefore submitted that Tang et al do not anticipate the nucleic acid molecule of claim 10, and that the rejection under 35 U.S.C. §102(b) based on Tang et al has been overcome. Reconsideration is respectfully requested.

Claims 1-7 and 9 were rejected under 35 U.S.C. §102(e) as anticipated by the Leach et al published U.S. application No. 2002/0082206. The Examiner referred to SEQ ID NO: 1343 and 1344.

This rejection is traversed and reconsideration is respectfully requested. The Leach et al application has a U.S. filing date of May 30, 2001, while the present application has a priority date of November 24, 2000, and, thus earlier than the U.S. filing date of Leach et al. While Leach et al claims priority to provisional application 60/208,427 filed May 30, 2000, the Examiner has not demonstrated that the Leach et al provisional application contains the

disclosures relied upon by the Examiner in rejecting the claims of this application. Therefore, the Examiner has not met the burden of establishing Leach et al as prior art with respect to the present application and the rejection must be withdrawn. Reconsideration is respectfully requested.

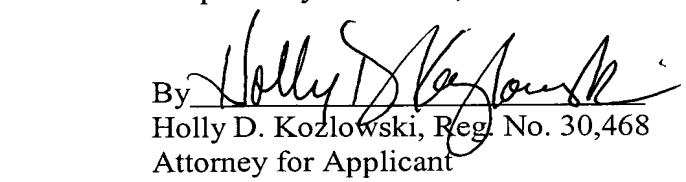
Further, the isolated nucleic acid molecule defined by claim 10, as discussed above, is selected from the group consisting of: (a) a nucleic acid molecule consisting of a nucleotide sequence as shown in SEQ ID NO: 1, or a nucleotide sequence which is at least 90% homologous with a nucleotide sequence as shown in SEQ ID NO: 1; (b) nucleic acid molecules consisting essentially of a nucleotide sequence capable of hybridizing, along its full length, under stringent hybridization conditions, to a nucleotide sequence complementary to the polypeptide coding region of a nucleic acid molecule as defined in (a); and (c) nucleic acid molecules consisting of a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence as defined in (a) or (b).

It appears that SEQ ID NO: 1343 of Leach et al contains 1375 nucleotides. Accordingly, the isolated nucleic acid molecule selected from the group consisting of (a), (b) and (c) as set forth in claim 10 is clearly distinguishable from Leach et al. Applicant finds no teaching or reference by Leach et al of a nucleic acid molecule consisting of a nucleotide sequence as claimed. Rather, Leach et al provide a significantly larger nucleotide sequence. Thus, Leach et al do not disclose each element of claim 10 and therefore do not support a rejection of this claim, or the claims dependent thereon, *Alco Standard Corp. v. TVA*, supra.

It is therefore submitted that Leach et al do not anticipate the nucleic acid molecule of claim 10, and that the rejection under 35 U.S.C. §102(b) based on Leach et al has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§ 101, 102, and 112, first paragraph, and places the present application in condition for allowance. Reconsideration is requested.

Respectfully submitted,

By 

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